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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/531,161	04/12/2005	Irina Shcherbakova	50821/5	4723
7590 Kevin B Laurence Stoel Rives One Utah Center 201 South Main Street Suite 1100 Salt Lake City, UT 84111	01/16/2007		EXAMINER TRUONG, TAMTHOM NGO	
			ART UNIT 1624	PAPER NUMBER
SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE		
3 MONTHS	01/16/2007	PAPER		

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary

Application No.

10/531,161

Applicant(s)

SHCHERBAKOVA ET AL.

Examiner

Tamthom N. Truong

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on amendment of 12-14-06.
2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-14 and 16-19 is/are pending in the application.
4a) Of the above claim(s) _____ is/are withdrawn from consideration.
5) ☐ Claim(s) _____ is/are allowed.
6) ☒ Claim(s) 1-14 and 16-18 is/are rejected.
7) ☐ Claim(s) _____ is/are objected to.
8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date 7/31/06 & 12/14/06.
4) ☒ Interview Summary (PTO-413)
Paper No(s)/Mail Date 11-7-06.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____

FINAL ACTION

Applicant's amendment of 12-14-06 has been fully considered. The amended claims 14 and 17 have overcome the previous rejection of 112/1st paragraph. Therefore, said rejection is now withdrawn. The amended claim 1 has overcome the previous rejection of 112/2nd paragraph, but not the 102 rejection based on **Wright, Jr. et. al.** (US'502). Thus, the 112/2nd rejection is now withdrawn, but the 102 rejection is maintained.

The new limitation in claim 1 also raises the following new ground of rejection.

Claim 15 has been cancelled.

Claims 1-14 and 16-19 are pending.

Claim Rejections - 35 USC § 112, Second Paragraph

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

1. Claims 1-14 and 16-19 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The limitation of "the compound has a Calcium Receptor Inhibitor Assay IC₅₀ value of 30 μ M or lower" renders the above claims indefinite because it is not clear what subset of compound is intended. Also, the phrase "or lower" does not have definite metes and bounds, and technically includes 0. It is not clear what assay conditions are needed to obtain such an IC₅₀

value. Thus, various factors could yield the same IC₅₀ value for different set of compounds. Moreover, it has been decided by the court in *In re Venezia* (189 USPQ 149) that functional language is proper when it serves “to precisely defined present structural attributes of interrelated components parts of the claimed assembly.” (M.P.E.P 2173.05(g)). In the instant case, the functional language does not define any structural attributes, and thus renders said claims indefinite.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. Claims 1-3, 5-9 and 13 are rejected under 35 U.S.C. 102(b) as being anticipated by **Wright, Jr. et. al.** (US'502). On column 4, the 10th and 16th compounds in Table 1 reads on compounds of the instant claims 1-3, 5-9, and the pharmaceutical composition of the instant claim 13 when the instantly claimed quinazolinone formula has the following substituents:

- i. X¹ is C;
- ii. R¹, R³ and R⁴, each is hydrogen; or
- iii. R² is halogen;
- iv. R⁵ is hydrogen;

- v. R^6 is $-(CH_2)_n-X^2-R^7$;
- i. X^2 is an alkyl group; $n = 2$;
- ii. R^7 is an aromatic group (i.e., *pyridyl* group).

Note, the limitation of IC_{50} value in the instant claim 1 does not overcome the above compounds because said value would inherently be determined by the structure.

Allowable Subject Matter

3. Claim 19 is allowable. Claim 19 recites species with the combination of *hydroxyl-phenyl* at the 2nd position, and *phenyl(or pyridyl)-ethyl* at the 3rd position of the quinazolinone ring, which is not taught or fully suggested by the prior art of record.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event,

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however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

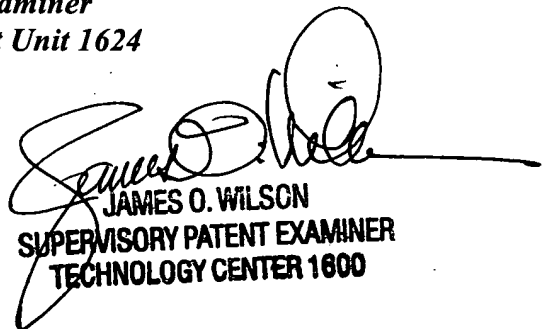
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Tamthom N. Truong whose telephone number is 571-272-0676. The examiner can normally be reached on M, T and Th (9:00-5:30).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James O. Wilson can be reached on 571-272-0661. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.


Tamthom N. Truong
Examiner
Art Unit 1624

1-5-07


JAMES O. WILSON
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